UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

SUBJECT: RCRA Laboratory Audit Inspection Guidance Document

FROM: J. Winston Porter
Assistant Administrator

TO: Waste Management Division Directors
Environmental Services Division Directors
Regions I - X

Attached is a copy of the final RCRA Laboratory Audit Inspection Guidance Document (LAI). The LAI is one component of the multi-phased RCRA ground-water monitoring enforcement process. The guidance is closely related to RCRA Ground-Water Monitoring Operation and Maintenance Guidance (O&M) and the RCRA Comprehensive Ground-Water Monitoring Evaluation Guidance Document (CME). The LAI closes the loop on guidance that is needed by enforcement officials to review the design and operation of ground-water monitoring systems.

The development of the LAI was assisted by a workgroup composed of both Headquarters and Regional personnel. Their combined experience in RCRA inspections and laboratory practices is reflected in the technical quality of this document. The LAI was further reviewed by the Office of Enforcement and Compliance Monitoring (OECM) and the Office of General Counsel (OGC) to ensure its regulatory soundness.

The LAI is intended to assist RCRA inspectors in conducting laboratory audits. The LAI provides a framework for evaluating the reliability of the laboratory analysis performed by RCRA facilities on their ground-water monitoring samples. The LAI will generally involve a review of the following:

- owner/operator sampling and analysis plan or permit,
- laboratory staffing, equipment, and maintenance program,
- Laboratory QA/QC procedures and sample tracking system, and
- Analytical methodologies used (if qualified enforcement personnel and resources are available).

OSWER 9950.4

RCRA LABORATORY AUDIT INSPECTION GUIDANCE DOCUMENT

(RCRA Ground-Water Monitoring Systems)

FINAL

RCRA Enforcement Division
Office of Waste Programs Enforcement
U.S. Environmental Protection Agency

September 1988

RCRA Laboratory Audit Inspection Guide
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PART ONE

Pre-Inspection Planning

PART ONE

The laboratory inspector and the enforcement official will meet and complete four tasks. These tasks are: 1) review permitting and enforcement actions taken to date involving the owner/operator; 2) review the owner/operator's sampling and analysis program; 3) review the owner/operator's Laboratory QA/QC procedures; and 4) prepare site-specific inspection instructions.

Laboratory Name: _____

Name of Laboratory Contact: _____

Phone Number: ( ) _____

Address of Laboratory: _____

_____

_____

Name, RCRA identification number, address, phone number, and contact of owner/operator using laboratory:

_____

_____

_____

_____

_____

Name of inspector(s): _____

Date(s) of inspection: _____

Does the owner/operator have:

Interim Status (Go to 1a)
- ☐ detection monitoring
- ☐ assessment monitoring
- ☐ corrective action (§3008(h))

Permit Status (Go to 1b)
- ☐ detection monitoring
- ☐ compliance monitoring
- ☐ corrective action

1a. Past action taken at facility (interim status)

Type	Date(s)
• Operation and Maintenance	_____
• Comprehensive Ground-water Monitoring Evaluation	_____
• Case Development Inspection	_____
• RCRA Facility Assessment	_____
• Compliance Evaluation Inspection	_____
• Past reviews of the laboratory (i.e., CWA, LAI, CLP, etc.)	_____
• Results of performance audit samples	_____

Complete the following regarding the actions listed above:

- Do you have a copy of completed inspection reports and/or site studies?

  ☐ Yes ☐ No

- For each, summarize deficiencies regarding the owner/operator's sampling and analysis program (i.e., deficiencies relating to the owner/operator's ability to generate high quality monitoring data).

Go To 2a

1b. Actions taken at the facility to date (permit status)

Type	Date(s)
• Permit Issuance	_____
• Operation and Maintenance Inspection	_____
• Comprehensive Ground-water Monitoring Evaluation	_____
• Case Development Inspection	_____
• Compliance Evaluation Inspection	_____
• RCRA Laboratory Audit Inspection	_____

Complete the following in regard to the actions listed above:

- Do you have a copy of the permit and copies of inspection reports completed after permit issuance?

☐ Yes ☐ No

- Summarize the deficiencies identified after permit issuance regarding the owner/ operator's sampling and analysis program?

Go To 2b

2a. Identify enforcement actions issued to the facility in regard to interim status violations

Action	Date(s)
• §3008(a) complaint/order	_____
• §3013 order	_____
• §3008(h) complaint/order	_____
• §7003 complaint/order	_____
• Referral for litigation	_____

Complete the following regarding the actions listed above:

- For each, identify if the enforcement action focused on the owner/operator's sampling and analysis program. Summarize relevant requirements imposed on the owner/operator.

Go To 3

2b. Identify enforcement actions issued to the facility after the permit issuance date

Action	Date(s)
• §3008(a) complaint/order	_____
• §3008(h) complaint/order (issued prior to permit)	_____
• §3013 order	_____
• §7003 complaint/order	_____
• Referral for litigation	_____
• Permit revocation	_____

Complete the following regarding the actions listed above:

- For each, identify if the enforcement action focused on the owner/operator's sampling and analysis program. Summarize relevant requirements imposed on the owner/operator.

Go To 3

3. **Review and summarize the owner/operator's sampling and analysis plan. (NOTE: Revise or add to the table if permit conditions dictate a different requirement the owner/operator must follow.)**

Does The Plan:	Y/N/NA
Name an individual as the Laboratory Quality Assuarance Manager and specify job requirements relating to the position?	
Include a current summary of training, experience, and job description for each member of the laboratory staff?	
Describe quality control paperwork flow and identify those who are authorized to approve data and results?	
Identify who is responsible for corrective procedures?	
Describe the laboratory's system for developing or revising technical procedures and identify those who have authorization for doing so?	
Require dating chemicals upon receipt and using them on a first-in, first-out basis?	
Specify use of reagent grade or high purity chemicals to prepare standards?	
Require testing of chemicals used in analyses to ensure they contain no contaminants which may interfer with analyses?	
Require labeling of all reagents and solutions to indicate identity, concentration, storage requirements, preparer's name, preparation date, and expiration date?	
Require checking and recording of the conductivity of distilled/demineralized water on a routine basis?	
Specify use of reagent grade water as required by specific method?	
Specify use of distilled water as required by specific method?	
Require discontinuing the use of any reagents/solutions that have passed the expiration date on the label?	
Require storage of samples and/or standards containing the analyte(s) of interest in areas other than where trace analysis is performed?	
Require storage of standards separately from sample extracts?	
Specify the use of analysis request sheets?	

(3. Con't) Does The Plan:	Y/N/NA
Include and mandate the use of written calibration procedures, analytical procedures, computational procedures, quality control procedures, and operating procedures?	
Require daily instrument calibration?	
Specify the use of standard curves and check samples for calibration purposes?	
Specify the use of logs to record all instruments and equipment checks?	
Describe when an analytical system is "out of control" through the use of matrix spikes and/or surrogates?	
Require corrective procedures when an analytical system is "out of control?"	
Specify the use of Class A type glassware?	
Name an individual to log-in samples in the laboratory?	
Describe storage requirements for incoming samples?	
Specify the assignment of laboratory numbers to all incoming samples?	
Require maintenance of proper temperatures for incoming samples?	
Describe chain-of-custody procedures the laboratory will use?	
Specify the use of a master schedule sheet or log book of all samples being analyzed, indexed by laboratory numbers, client, date of arrival, and analysis to be performed?	
Specify the use of sample analysis request sheets?	
Specify maximum holding times for samples?	
Require the daily recording of temperature in cold storage areas?	
Specify the use of matrix spikes (one per analytical batch per matrix, or every twenty samples, whichever is more frequent)?	
Require the use of replicates and laboratory duplicates (one per analytical batch per matrix, or every twenty samples, whichever is more frequent)?	

(3. Con't) Does The Plan:	Y/N/NA
Require the use of blanks (one per analytical batch per matrix, or every twenty samples, whichever is more frequent)?	
Require the use of field duplicates (one per analytical batch, or every twenty samples, whichever is more frequent)?	
Require the use of check samples (one per analytical batch, or every twenty samples, whichever is more frequent)?	
Require the use of surrogates for volatile and semi-volatile organics and pesticides (add to every blank, standard, sample, and QC sample)?	
Require the use of column check samples (absorbent chromatography and back-extractions of organic compounds—one per batch of absorbent)?	
Require the use of standard curves for AA, ICP, GC, and other analytical methods?	
Require GC/MS instrument performance check (initial five point calibration is to be verified with a single point calibration once every twelve hours of instrument operation, and if the sensitivity and linearity criteria are not met, a new five point initial calibration must be generated)?	
Require owner/operator to have a system to examine validate raw data from a commercial laboratory?	

Comments on Sampling and Analysis Plan and Site Specific Instructions

Comments on Sampling and Analysis Plan and Site Specific Instructions (continued)

SECTION ONE

OVERVIEW OF THE RCRA LABORATORY AUDIT INSPECTION

1.1 Enforcement Objectives of the RCRA Laboratory Audit Inspection

The 1989 RCRA Implementation Plan introduces the RCRA Laboratory Audit Inspection (LAI) as a new type of inspection. The LAI reinforces EPA's commitment to the proper implementation of the RCRA ground-water monitoring regulations. The LAI guide complements existing ground-water monitoring enforcement guidance documents issued by EPA, including the *RCRA Ground-Water Monitoring Technical Enforcement Guidance Document* (September 1986), the *RCRA Ground-Water Monitoring Compliance Order Guide* (August 1985), and the *Operation and Maintenance Inspection Guide—RCRA Ground-Water Monitoring Systems* (March 1988).

The LAI guide, in essence, closes the loop on guidance that is needed by enforcement officials to review the design and operation of RCRA ground-water monitoring systems. It focuses on the laboratory and is designed to ensure that the laboratories which perform ground-water analyses generate reliable analytical data. Specifically, EPA has designed the LAI to achieve the following enforcement objectives:

- determine that the owner/operator's personnel who perform analyses on ground-water samples are analyzing them in accordance with proper procedures; e.g.:

    - in accordance with the owner/operator's 40 CFR Part 265 (interim status) *Sampling and Analysis Plan*; or

    - in accordance with conditions associated with the sampling and analysis section of the owner/operator's RCRA permit; or

    - in accordance with conditions associated with the sampling and analysis section of the workplan in a Corrective Action Order;

- determine that laboratories which perform analyses on RCRA ground-water monitoring samples are capable of generating high quality analytical data;

- identify violations in regards to the owner/operator's laboratory program and/or trigger a more thorough scrutiny of laboratory practices through the initiation of a Case Development Inspection; and

- provide a mechanism to investigate concerns over anomolies in owner/operator ground-water data sets or concerns over the quality of data generated by individual laboratories.

1.2 Regulatory Basis for the RCRA Laboratory Audit Inspection

The authority of EPA to require an owner/operator to implement procedures to generate high quality analytical data for ground-water samples is firmly rooted in regulations under 40 CFR Parts 265, 264 and 270. **Table 1** lists the most pertinent regulatory requirements related to ground-water analytical programs. These regulations require owner/operators to implement a comprehensive program to ensure the generation of high quality analytical data associated with ground-water samples. RCRA 3008(a) gives EPA the authority to take enforcement action against those owner/operators who fail to comply with these regulations.

Sections 265.92 and 264.97 are particularly important regulatory sections in regards to ground-water sampling and analysis. Section 265.92 requires the owner/operator (interim status) to prepare and follow a written sampling and analysis plan. Similar provisions are to be written into RCRA permits as per the requirements of Section 264.97. In either case, specific details as to the analytical procedures and quality control procedures the owner/operator will follow should be described in written form. Section 1.4 of this guidance describes the type of quality control procedures owner/operators should have in place at their laboratories. These quality control procedures will be the focal point for much of the effort in the RCRA Laboratory Audit Inspection.

Part Three of the laboratory audit inspection form (Appendix A) illustrates how the regulations in **Table 1** relate to violations EPA is likely to encounter. It is important to understand that the generation of reliable analytical data is the sole responsibility of the owner/operator. An owner/operator cannot escape this obligation by contracting with a commercial laboratory. *Questionable performance on the part of the commercial laboratory will always be viewed by EPA as questionable performance on the part of the owner/operator.* Where appropriate, EPA will initiate enforcement actions against the owner/operator in cases where the contracted commercial laboratory is generating questionable quality data or is engaging in questionable laboratory practices.

TABLE 1
REGULATORY BASIS FOR THE LABORATORY AUDIT INSPECTION

§264.97(d)
"The ground-water monitoring program must include consistent sampling and analysis procedures that are designed to ensure monitoring results that provide a reliable indication of ground-water quality below the waste management area. At a minimum the program must include procedures and techniques for

(1) Sample collection;
(2) Sample preservation and shipment;
(3) Analytical procedures; and
(4) Chain of custody control."

§264.97(e)
"The ground-water monitoring program must include sampling and analytical methods that are appropriate for ground-water sampling and that accurately measure hazardous constituents in ground-water samples."

§270.14(c)(6)(iv)
"A description of proposed sampling analysis and statistical comparison procedures to be utilized in evaluating ground-water monitoring data." (Detection Monitoring)

§270.14(c)(7)(vi)
"A description of proposed sampling, analysis, and statistical comparison procedures to be utilized in evaluating ground-water monitoring data." (Compliance Monitoring)

§265.92(a)
"The owner or operator must obtain and analyze samples from the installed ground-water monitoring system. The owner or operator must develop and follow a ground-water sampling and analysis plan.... The plan must include procedures and techniques for:

(1) Sample collection;
(2) Sample preservation and shipment;
(3) Analytical procedures; and
(4) Chain of custody control."

1.3 Relationship of the Laboratory Audit Inspection to Other RCRA Inspections

There are three types of RCRA inspections that relate to the RCRA Laboratory Audit Inspection. They are: 1) the *Comprehensive (Ground-Water) Monitoring Evaluation (CME);* 2) the *Operation and Maintenance Inspection—RCRA Ground-Water Monitoring Systems (O&M);* and 3) the *RCRA Case Development Inspection (CDI).* Each of these inspections are cited in the FY 1989 RCRA Implementation Plan.

EPA designed the Comprehensive Ground-Water Monitoring Evaluation (CME) to determine whether a facility's RCRA ground-water monitoring system has been properly designed and constructed, and is being sampled in such a manner to provide representative ground-water samples. Some activities included in a CME are:

- evaluation of the owner/operator's hydrogeologic data and site characterization,
- review of the design of the monitoring well network,
- evaluation of the construction of the monitoring wells,
- review/observation of the owner/operator's sampling program,
- review of chain of custody procedures, and
- review of the statistical techniques used and conclusions drawn from the detection/assessment monitoring data.

EPA designed the Operation and Maintenance (O&M) inspection to ensure that the monitoring network is continuing to perform as designed. The O&M does not involve a re-evaluation of the design of the system, but focuses on the field performance of the owner/operator's staff in collecting ground-water samples, and on the evaluation of the continued integrity of the owner/operator's monitoring system. The inspection will confirm, for example, that the wells continue to yield low turbidity samples, the well casings are structurally sound, and continue to isolate the formations being monitored and that the purging and sampling equipment are functioning properly.

The Case Development Inspection (CDI) is a comprehensive effort to compile evidence to support litigation or administrative enforcement actions against an owner/operator or to establish the need for such actions. Case Development Inspections are often performed on an as-needed basis in response to the results from other RCRA inspections (e.g., LAI, O&M, CEI, CME).

The Laboratory Audit Inspection (LAI) will generally involve a review of the following:

- the owner/operator's sampling and analysis plan;
- the laboratory staffing, equipment and maintenance program;
- laboratory QA/QC procedures and sample tracking system; and
- the analytical methodologies used (see Test Methods for Evaluating Solid Waste (SW-846)).

It is important to note that EPA has not designed the LAI to be a certification program. Rather, it is a tool to determine whether improper or inadequate laboratory procedures have resulted in the generation of inaccurate ground-water monitoring data. The purpose of the LAI is to confirm that the owner/operator is fulfilling the responsibilities of the RCRA program—not to certify or give the laboratory in question an EPA "seal of approval" for RCRA work.

The results of a CME or O&M inspection may prompt the enforcement program to initiate an LAI. For example, the findings of an O&M inspection may reveal that analytical data from split samples differs significantly. The RCRA inspector would perform an LAI to determine whether or not laboratory error caused the discrepancy. In some instances, laboratory results may not indicate contamination even though such contamination is evident down-gradient from the facility. In such a case, an LAI would be conducted to determine whether improper analytical practices caused false negative results. Widely varying analytical results or unsatisfactory detection limits may also indicate the need for an LAI.

EPA has designed the CME, O&M, and the LAI to form a comprehensive and ongoing evaluation of the design and operation of RCRA ground-water monitoring systems. The CME, O&M, and LAI form a system of checks to ensure that RCRA ground-water monitoring systems are designed properly, are operated properly, and produce high-quality data to support regulatory and compliance decision-making.

The number of laboratory audit inspections to be conducted annually is left to the discretion of authorized State and EPA enforcement officials. There are, however, situations that should prompt an enforcement official to consider conducting a Laboratory Audit Inspection. These situations include:

- where a CME or an O&M inspection has uncovered anomalies or patterns of concern in the owner/operator's data set;

- where the enforcement official suspects the owner/operator's waste management unit is leaking, but the monitoring data indicates no evidence of leaks; and

- where the enforcement official is concerned that an individual laboratory is chronically generating inconsistent or questionable analytical data.

1.4 Laboratory Quality Control Programs for Ground-Water Analysis

The generation of high quality analytical data was of paramount concern to EPA when the Agency promulgated the RCRA ground-water monitoring regulations. The regulations specify that owner/operators must prepare and follow written plans (interim status) in regards to the sampling and analytical procedures they will follow in generating ground-water monitoring data. EPA's view is that an owner/operator's quality control (QC) program begins at the conception of the monitoring program, continues through collection and storage of samples, includes all phases of chemical and physical analyses and extends through the interpretation and compilation of data results.

In order to ensure the generation of reliable monitoring data, the owner/operator must follow standard operating procedures (SOPs) written into the sampling and analysis plan (or in the permit for permitted facilities). The *RCRA Ground-Water Monitoring Technical Enforcement Guidance Document; Test Methods for Evaluating Solid Wastes* (SW-846, November 1986); and the *Operation and Maintenance Inspection Guide—RCRA Ground-Water Monitoring Systems* describe in detail SOPs related to the collection of ground-water samples. In addition, an adequate sampling and analysis plan should include SOPs for all routine laboratory tasks.

Laboratory SOPs should be **comprehensive enough** to establish the traceability of standards, instrumentation, samples and environmental data; **simple enough,** so a user with basic education, experience, and/or training can properly use them; **complete enough** so the user can follow the directions in a stepwise manner; and **consistent** with sound scientific principles and with instrument manufacturers' instruction manuals. SOPs should also provide documentation sufficiently complete to record the performance of all tasks and their results, explain the cause of missing data, and demonstrate the validation of data each time they are recorded, calculated or transcribed.

An owner/operator's sampling and analysis plan should include SOPs and quality assurance provisions which address the following:

- qualifications of the laboratory's personnel and the organizational structure of the laboratory;
- procedures for maintaining laboratory supplies and equipment;
- procedures for equipment calibration;
- procedures for sample handling (collection, preservation, etc.);
- analytical methodologies used;
- quality control procedures; and
- procedures for data handling, reporting, and recordkeeping.

Although there are no regulatory minimum qualifications, the inspector should use his discretion to determine if adequate training and experience exists in the laboratory.

1.4.1 Qualifications of Laboratory Staff and Organizational Considerations

A laboratory should be organized to ensure the generation of reliable data. **Figure 1** is an example of a laboratory organizational chart. Suggested levels of qualifications for the laboratory staff have been, in this case, attached to each position. Although there are no regulatory minimum qualifications, the inspector should use his discretion to determine if adequate training and experience exists in the laboratory.

Every owner/operator's sampling and analysis plan should reflect organizational decisions made by the laboratory. Specifically, the plan should:

- describe the laboratory's organizational structure;

- identify a quality assurance coordinator or supervisor;

- describe quality control paperwork flow and identify those who are authorized to approve data and results;

- identify those who are responsible for corrective procedures; and

- describe the laboratory's system for developing or revising technical procedures or documents—and identify those who have authority to do so.

1.4.2 Procedures for Maintaining Laboratory Supplies and Equipment

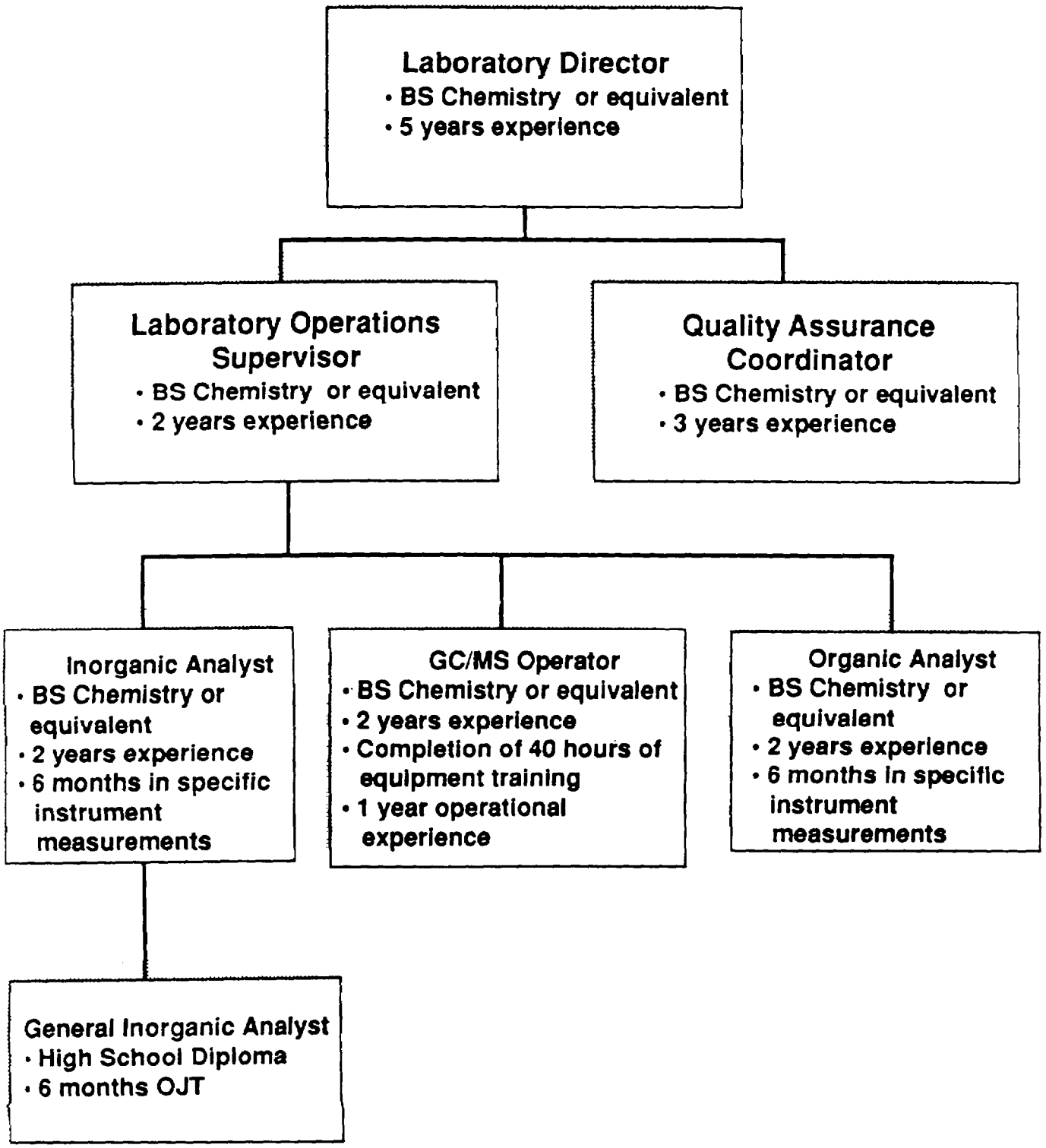
The laboratory should document purchasing guidelines for all equipment and reagents having an effect on data quality. Similarly, performance specifications should be documented for all items of equipment having an effect on data quality. Once any item which is critical to the analysis such as in-situ instrument or reagent is received and accepted by the organization, the laboratory should retain documentation of the type, age, and acceptance status of the item. Reagents should be dated upon receipt in order to establish their order of use and to minimize the possibility that the reagents will exceed their useful shelf life.

Preventive maintenance procedures should be written for each measurement system and required support equipment. When maintenance activity is necessary, the laboratory should document it on standard forms maintained in logbooks. A history of the maintenance record of each system serves as an indication of the adequacy of maintenance schedules and parts inventory.

1.4.3 Equipment Calibration

Calibration is the process of establishing the relationship of a measurement system output to a known stimulus. In essence, calibration is a reproductive reference point to which all sample measurements can be correlated. The laboratory should prepare a calibration SOP to include provisions for documentation of frequency, conditions, standards, and records reflecting the calibration history of measurement systems. The accuracy of the calibration standards is an important point to consider since all data will be in reference to the standards used. The laboratory should routinely follow a SOP for verifying the accuracy of all working standards

Figure 1
Example Laboratory, Inc.
Organization Chart



against primary grade standards. The laboratory's SOP should also specify the corrective procedures that the laboratory will take when an analytical system is determined to be out of control.

1.4.4 Sample Handling Procedures

Samples taken to satisfy regulatory requirements must comply with "chain-of-custody" procedures. At a minimum, the laboratory should address sample custody procedures in the QA/QC SOP including identification of a sample custodian, development of a sample custody sheet and specification of sample custody procedures.

A responsible person should be identified to act as sample custodian at the laboratory facility. The sample custodian should be authorized to sign for incoming field samples, obtain documents of shipment (e.g., the bill of lading number or mail receipt), and verify that data is entered onto the sample custody records. The laboratory should prepare a laboratory sample custody log consisting of serially numbered standard lab-tracking report sheets and should specify laboratory sample custody procedures for sample handling, storage and disbursement for analysis.

1.4.5 Laboratory Quality Control

The quality control procedures the laboratory uses should be described in its SOPs. The purpose of laboratory QC is to indicate the quality of the data as it is being produced. Indications of the data quality are often looked at in terms of accuracy, precision, and detection limit of the analyses.

Accuracy may be thought of as a measurement indicating the closeness of an individual measurement, or an average of a number of measurements to the true value. Accuracy is generally represented as percent recovery. Precision is defined as a measure of reproducibility among individual measurements of the same property under similar conditions. Instrument and overall method precision are often represented as coefficient of variation, standard deviation, and relative standard deviation. Precise and accurate results are obtained by instituting a QC program which demands that the degree of variability of all operating parameters be kept within specified limits.

Table 2 contains analytical QC requirements and their frequency of application that are typical of a laboratory QC program. The QC provisions contained in

TABLE 2
QUALITY CONTROL REQUIREMENTS AND FREQUENCY OF APPLICATION

QC Parameter	Freqency	Comments
Matrix spikes	1 per analytical batch per matrix or every 20 samples, whichever is more frequent	
Replicates & laboratory duplicates	1 per analytical batch per matrix or every 20 samples, whichever is more frequent	Replicate samples are separate aliquots taken from the same sample container in the laboratory and analyzed independently. Analysis of two replicates indicates the existence of gross errors. In cases where aliquoting is impossible (i.e., volatiles) duplicate samples must be taken for replicate analysis
Blanks (field, trip, equipment)	1 per analytical batch per matrix or every 20 samples, whichever is more frequent	
Field duplicates	1 per analytical batch per matrix or every 20 samples, whichever is more frequent	Field duplicate samples are two separate samples taken from the same sampling point in the field (i.e., in separate containers and analyzed independently)
Check sample	1 per analtyical batch or every 20 samples, whichever is more frequent	
Surrogates	Add to every blank, standard, sample, and QC sample	Only for volatile and semi-volatile organics and pesticides
Column check sample	1 per batch of adsorbent	Applies to absorbent chromatography and back extractions of organic compounds
Column check sample blank	1 per batch of adsorbent	Applies to adsorbent chromatography and back extractions of organic compounds
Standard curves	Refer to specific method for necessary periodic calibration	Applies to AA, ICP and GC Methods
GC/MS instrument performance criteria	Initial 5 point calibration is to be verified with a single point calibration once every 12 hours of instrument operation and if the sensitivity and linearity critera are not met, a new 5 point initial calibration must be generated	Performed to meet tuning criteria of the instrument as specified in the GC/MS methods. Organic analytes shall be checked with 4-bromofluorobenzene (BFB) for determination of volatiles and with decafluorotriphenylphophine (BFTPP) for determination semivolatiles

Table 2 will help to ensure that generated data is of known accuracy and precision. If accuracy and precision fall outside of specified limits, corrective procedures should be taken.

1.4.6 Data Handling, Reporting, and Recordkeeping

Data handling, reporting, and recordkeeping procedures should be included in a laboratory's SOP. Data handling and reporting includes all procedures used to record data on standard forms and in laboratory notebooks. The reporting format for different types of bench data should be described and forms provided. Notebooks should be bound with numbered pages and contents should be specified.

Laboratory recordkeeping makes possible the reexamination of a set of data at a future time if various aspects of the analysis are called into question. Data validation procedures, defined ideally as a set of computerized and manual checks applied at various appropriate levels of the measurement process, should be in written form and clearly defined for all measurement systems. Criteria for data validation must be documented and include limits on:

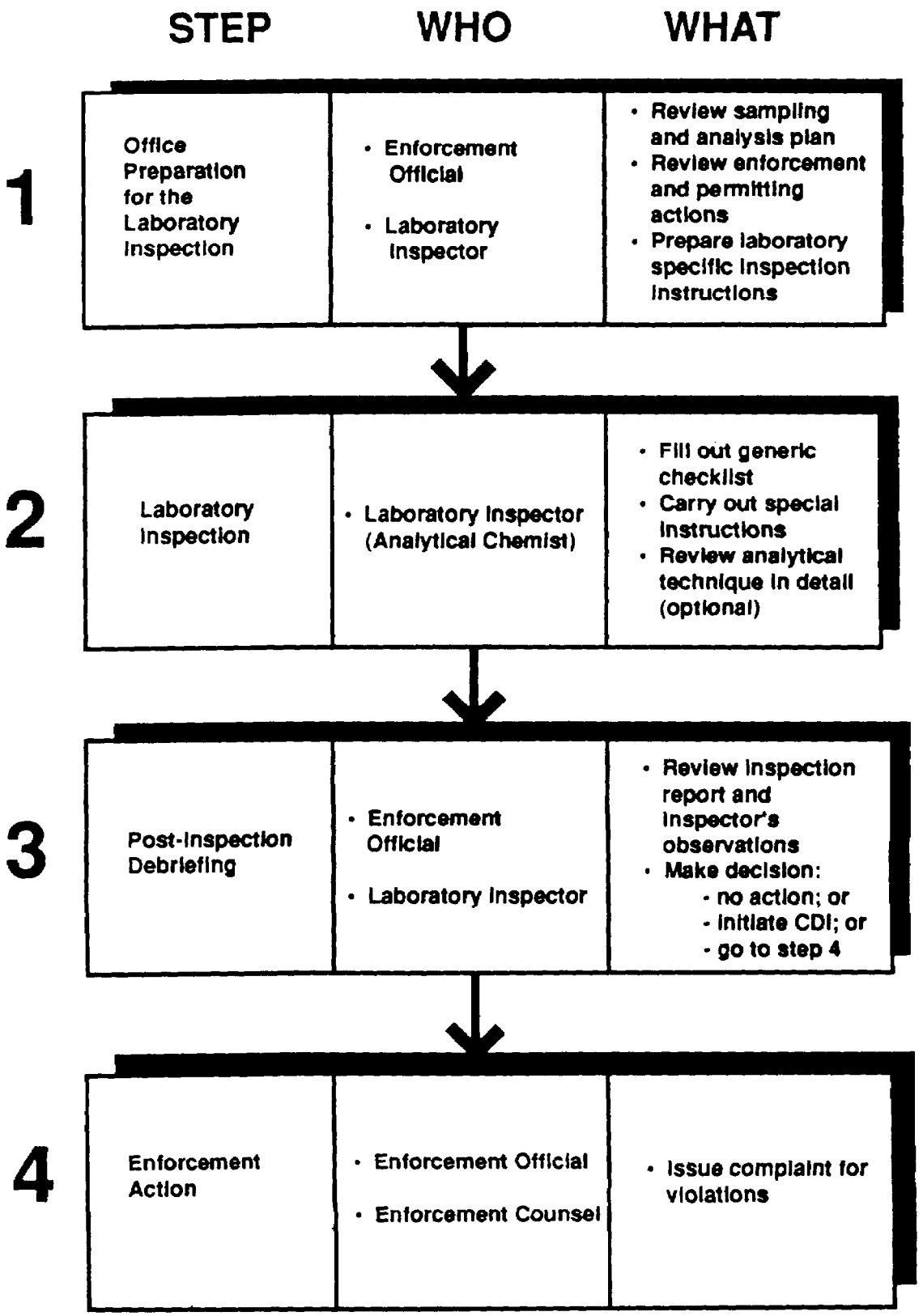
- operation parameters such as GC conditions;
- calibration data;
- special checks unique to each measurement, e.g., successive values/averages;
- statistical tests, e.g., outliers; and
- manual checks such as hand calculations.

Data validation activities (GC operating conditions, analytical precision, etc.) should be recorded on standard forms in a logbook.

1.5 The RCRA Laboratory Audit Inspection Process

Developing enforcement cases relating to the RCRA Laboratory Audit Inspection requires the participation of a variety of persons, including the laboratory inspector (analytical chemist or equivalent); the enforcement official and enforcement counsel. **Table 3** illustrates the generic process Regions and States should follow in conducting a laboratory audit inspection. It is important to note that **Table 3** does not represent a prescribed set of activities states and regions must follow. The states and regions may, in fact, use variants of the generic process in **Table 3.**

TABLE 3
THE RCRA LABORATORY AUDIT INSPECTION



In Step 1, the laboratory inspector and the enforcement official will meet. The purpose of their meeting is to plan out the laboratory portion of the laboratory audit inspection. They will review the owner/operator's sampling and analysis plan, review enforcement and permitting actions taken to date at the facility and prepare a list of laboratory-specific observations the inspector should make. After completion of Step 1, the inspector will be prepared to inspect the owner/operator's laboratory.

In Step 2, the inspector will visit the laboratory. The laboratory inspector will complete the laboratory audit inspection checklist and carry out any special instructions generated during Step 1.

In Step 3, the laboratory inspector and the enforcement official will meet again. They will review the laboratory audit inspection checklist and discuss the inspector's observations. The enforcement official will make a decision to pursue one of the following actions:

- issue a complaint; or
- initiate a Case Development Inspection; or
- take no further action.

If enforcement action is warranted, the enforcement official will meet with counsel. They will prepare and issue a complaint to the owner/operator for violations detected during the laboratory audit inspection.

SECTION TWO

OFFICE PREPARATION FOR THE LABORATORY INSPECTION

The laboratory inspector and the enforcement official will work together in preparation for the laboratory inspection. There are four tasks the laboratory inspector and the enforcement official must complete prior to the inspection. They are:

1. review and summarize the enforcement and permitting actions taken to date regarding the owner/operator's laboratory program;

2. review and summarize the owner/operator's sampling and analysis plan (or permit conditions);

3. review the owner/operator's laboratory QA/QC procedures; and

4. prepare laboratory-specific inspection objectives.

The laboratory inspector and the enforcement official will use Part One of the RCRA Laboratory Audit Inspection Form (RCRA Ground-Water Monitoring *Systems)* to guide them through the tasks listed above. The form has been constructed so that when the laboratory inspector and enforcement official complete it, they will know:

- the laboratory procedures and techniques the owner/operator uses to ensure the generation of reliable monitoring data; and

- the existence and nature of any prior or on-going permitting or enforcement action which may affect the laboratory inspection.

SECTION THREE

THE LABORATORY INSPECTION

The laboratory inspector will complete a number of tasks during the inspection. The tasks are:

1. review the qualifications of the laboratory's personnel and the organizational structure of the laboratory;

2. review the laboratory's procedures for maintaining supplies and equipment;

3. review calibration procedures at the laboratory;

4. review sample handling procedures at the laboratory;

5. review the laboratory's quality control program;

6. review the laboratory's procedures for data handling, reporting and recordkeeping; and

7. review analytical procedures used, and evaluate their appropriateness (optional task).

The laboratory inspector will use Part Two of the RCRA Laboratory Audit Inspection Form (RCRA Ground-Water Monitoring Systems) to guide him/her through the tasks listed above. The form has been constructed so that when the laboratory inspector completes it, the inspector will have:

- assessed whether the laboratory departed from written sampling and analysis procedures in the owner/operator's sampling and analysis plan (interim status) or in the owner/operator's RCRA permit (permit status); and

- identified deficiencies in the owner/operator's laboratory analysis program.

SECTION FOUR

COMPLIANCE DECISION MAKING

The laboratory inspector and the enforcement official will meet after the inspection and review parts one and two of the RCRA Laboratory Audit Inspection Form (RCRA Ground-Water Monitoring Systems). With the inspector's help, the enforcement official will use Part Three of the form to identify violations in the owner/operator's laboratory program. After completing this task, the enforcement official will choose one of the following options.

1. By virtue of the evidence collected by the laboratory inspector, there are sufficient grounds to take enforcement action: work with enforcement counsel to develop and initiate an enforcement action. Or—

2. By virtue of the evidence collected by the laboratory inspector, there may be sufficient grounds to pursue an enforcement action, however, additional or more detailed information is required: initiate a Case Development Inspection. Or—

3. The laboratory inspection has not uncovered significant compliance problems at the laboratory: do not pursue additional enforcement action.

PART TWO

Laboratory Inspection

After working through PART ONE, the enforcement official and the laboratory inspector should know:

- the laboratory procedures and techniques the owner/operator uses to ensure the generation of reliable analytical data; and

- the existence and nature of any prior or on-going permitting or enforcement action which may affect the laboratory inspection.

PART TWO

The inspector will complete a number of tasks during the laboratory inspection. The tasks are:

1) review the qualifications of the laboratory's personnel and the organizational structure of the laboratory;

2) review the laboratory's procedures for maintaining supplies and equipment;

3) review calibration procedures at the laboratory;

4) review sampling handling procedures at the laboratory;

5) review the laboratory's quality control program;

6) review the laboratory's procedures for data handling, reporting, and record-keeping; and

7) review analytical procedures used and evaluate their appropriateness (optional task).

1. Review the qualifications of the laboratory's personnel and the organizational structure of the laboratory	Y/N/NA
Has an individual been appointed as Quality Assurance Manager who:	
1) ensures adherence to QA requirements for sampling?	
2) ensures that all test and measuring equipment are properly calibrated?	
3) monitors logging in of samples?	
4) approves project plans, specific analyses, and final reports?	
5) maintains a copy of the master schedule sheet?	
6) maintains separate copies of all methods performed by the laboratory?	
7) maintains written and signed records of periodic inspections?	
8) maintains all Quality Assurance records in one location?	
Are qualified individuals employed to perform the required analyses?	
Are qualified individuals authorized to approve data and results?	

NOTES

2. Review the procedures for maintaining laboratory's supplies and equipment	Y/N/NA
Does the laboratory have sufficient facilities and adequate laboratory instruments to perform required analyses?	
Is the solvent storage area properly vented and appropriate for the retention of possible laboratory contamination?	
Are analytical and sample storage areas isolated from all atmospheric sources of solvent?	
Are chemicals dated upon receipt and used in a first-in, first-out basis?	
Are reagent grade or high purity chemicals used to prepare standards?	
Are chemicals being used in analyses tested to ensure that they contain no contaminants which may interfere with the analyses?	
Are all reagents and solutions labeled to indicate identity, concentration, storage requirements, preparer's name, preparation date, and expiration date?	
Does the laboratory have a source of distilled/demineralized water?	
Is the conductivity of distilled/demineralized water routinely checked and recorded?	
Is reagent grade water used for organic methods?	
Is distilled water used for inorganic methods?	
Are any reagents or solutions being used that have passed the expiration date on the label?	
To avoid contamination, are samples and/or standards containing the analyte(s) of interest stored or used in areas other than where trace analysis is performed?	
Are standards stored separately from sample extracts?	
Are the chemical handling areas either a stainless steel bench or an impervious material covered with absorbent materials?	
Are contamination free areas provided for trace level or organic analytical work?	
Are exhaust hoods provided to allow contamination-free work with volatile materials (i.e., venting for preparation, extraction, and analysis)?	

2. Review the laboratory's procedures for maintaining laboratory supplies and equipment (cont.)	Y/N/NA
Are adequate routinely needed in-house replacement parts available? (note: this is to ensure that the analytical equipment is not inoperable during a critical period)	
Is there a service record logbook maintained for each analytical instrument?	
Are instruments properly vented and/or appropriate traps in place as required?	
Are chemical waste disposal policies/procedures well-defined and followed by the laboratory?	

NOTES

3. Review calibration procedures at the laboratory	Y/N/NA
Are initial and daily instrument calibration procedures specified in QA/QC program?	
Are these procedures used in daily laboratory analysis as specified in the QA/QC program?	
Are standard curves and check samples used covering the analytical range of interest for calibrating analytical instruments to ensure that calibration accurately encompass the range of environmental samples?	
Is there a calibration log maintained of all instrument and equipment checks (i.e., date, analyst, calibration adjustment, etc., if any)?	
Are lab personnel assigned to perform the calibration procedures?	
If accuracy and precision of matrix spikes and/or surrogates fall outside of specific limits, is the analytical system deemed "out of control?"	
Does the laboratory stop analysis when an analytical system is deemed "out of control" and implement corrective procedures?	
Are corrective procedures clearly defined and documented?	
Is an individual assigned the responsibility of initiating corrective procedures if the individual deems it necessary?	
Does the laboratory require prompt notification of errors in reporting data or "loss" of a sample and a prompt request for resampling from the same point?	
Is the glassware used Class A type or calibrated to ensure that the amount marked on the glassware coincides with the amount delivered?	
Is the glassware periodically checked to ensure calibration is correct?	
Is the glassware cleaned correctly after each use to ensure that there will be no contamination with the next use?	
Is the analytical balance located away from drafts and areas subject to rapid temperature change?	
Has the balance been calibrated and checked within one year by a certified technician?	

NOTES

4. Review sampling handling procedures at the laboratory	Y/N/NA
Is an individual appointed to log in incoming samples?	
Does this individual know the sampling requirements (i.e. type of container, preservation, storage container, etc.) for each analysis or have that material available?	
If no individual(s) is appointed, are the individuals logging in samples aware of the sampling requirements for each analysis?	
Does this individual know the storage process for storage of incoming samples?	
Is a sample label affixed to each container?	
Do sample labels contain complete information in order to identify the sample and ensure that it has been sampled in the correct manner (i.e. facility name, station number, date sampled, time sampled, type of analysis requested, preservation used, signature of sampler, etc.)? (See Figure A-1.)	
Are samples collected in the type of container specified for each analysis?	
Are samples preserved as required and/or cooled to 4°C?	
Do samples which are shipped to the laboratory arrive at the correct temperature to ensure that the sample has remained in a preserved state?	
Are volatile samples received with no air bubbles?	
Are transport blanks, field blanks, and field duplications used as required?	
If so, are they identified as such?	
If used, are spiked samples identified?	
Is a chain of custody filled out and kept on file?	
Does the information on the sample tag and chain of custody match?	
Are laboratory numbers assigned to all incoming samples (including QC samples)?	
Does the laboratory maintain a master schedule sheet or logbook of all samples being analyzed, indexed by laboratory number, client, date of arrival, and analysis to be performed?	

FIGURE A-1
SAMPLE LABEL (EXAMPLE)

FIELD SECTION

Name of Facility: _____

Address: _____

Telephone: _____

Collector's Name: _____

Collector's Telephone: _____

Date Sampled: _____ **Time Sampled:** _____

Sample No.: _____

LABORATORY SECTION

Received by: _____

Date Received: _____

Analysis Required: _____

_____

Preservation Used:

_____

Storage Area:

_____

Special Handling Required:

_____

4. Review sampling handling procedures at the laboratory (cont.)	Y/N/NA
Is the laboratory number written on the sample label, the master schedule sheet, and any documents related to that sample?	
Are completed sample analysis request sheets available for each sample?	
Does each sample have a separate analysis request sheet for each analysis or group of analyses (i.e. organic, inorganic, etc.) to be performed? (Note: this is to ensure that each analyst who must perform an analysis on that sample will have a request sheet)	
After all analyses have been completed, are all request sheets attached together with all appropriate summary sheets for each analyses?	
Are all samples analyzed within correct amount of time?	
Are samples maintained at correct temperature until time of analysis?	
Are adequate facilities provided for storage of incoming samples, including cold storage?	
Are volatile samples stored separately from non or semi-volatile samples?	
Is the temperature of the cold storage recorded daily in a logbook?	
Are temperature excursions noted and are appropriate actions taken when required?	
If reused, are sample containers cleaned properly?	
Are the possession and handling of samples traceable from the time and date of collection to time and date of analysis and reporting?	
Demonstrate by tracing three samples available in the laboratory. Summarize by completing Figure A-2 (next page).	

NOTES

FIGURE A-2
Sample Tracing Form

Are the possession and handling of samples traceable from the time and date of collection to time and date of reporting?

Demonstrate by tracing three samples available in the laboratory: (Optional)

Sample I.D. Information	Sample A	Sample B	Sample C
Sample Number			
Facility Name			
Facility Address			
Sample Location			
Date Sampled			
Time Sampled			
Recipient at Lab			
Date Received			
Laboratory Number			
Analyses Requested			
Storage Procedure(s)			
Date of Analysis			
Analyst(s) I.D.			
Method(s) Used			
Date Results Reported			

NOTES:

5. Review the laboratory's quality control program	Y/N/NA
Is one matrix spike used for every analytical batch or every twenty samples, whichever is most frequent?	
Are accuracy results of matrix spikes and surrogates measured for each method to indicate the closeness of an individual measurement?	
Are precision results of sample replicates measured for each method to indicate reproducibility among individual measurements of the same property under similar conditions?	
Are the precision and accuracy results used to determine the control limits in which all operating parameters will be held?	
Are matrix spikes and surrogates analyzed to establish that the analytical measurement system is functioning properly with the desired sensitivity?	
Are these precision and accuracy results organized in the form of quality control charts?	
Are quality control charts or tabulation of mean and standard deviation or equivilent used to document validity of data on an as-run basis?	
Are matrix spikes and surrogates analyzed compared to control charts on an as-run basis to determine if the analysis is "in control?"	
Are check samples used, one per analytical batch or every 20 samples, whichever is more frequent?	
Is one blank used per analytical batch or every 20 samples, whichever is more frequent, to ensure that there are no contaminants which may interfere with the analysis?	
Is one field duplicate used per analytical batch or every 20 samples, whichever is more frequent?	
Are true duplicates prepared and analyzed per analytical batch or every 20 samples, whichever is more frequent (not reinjection or reanalysis of same set of standards/ samples)?	

5. Review the laboratory's quality control program (cont.)	Y/N/NA
Quality Control for Organic Analysis Is the analytical system calibrated each day according to the requirements of the method?	
Are these calibration standards analyzed, compared to control charts on an as-run basis to determine if the run is "in control?"	
Is a surrogate spike added to every blank, standard, sample, and QA sample?	
Are column checks samples and column check sample blanks used for each batch of absorbent?	
Are field blanks, transport blanks, and laboratory blanks used as needed, to ensure the water contains no contaminants which may interfere with analysis?	
Are laboratory method blanks extracted and analyzed with the same procedures used to extract and analyze samples?	
Are "true" duplicates prepared and analyzed for five percent of all samples (not reinjection of same set of samples)?	
Quality Control for Inorganic Analysis Is the precision of the system demonstrated by the analysis of replicate laboratory control standards each time the analytical system undergoes a major modification or prolonged period of inactivity?	
Are a minimum of three calibration standards covering the concentration range of the samples analyzed in order to prepare a standard calibration curve?	
Of these standards analyzed, is at least one at or below the MCL?	
For each day on which analyses are performed, is the standard calibration curve verified by use of at least a laboratory method blank and one standard curve?	
Is the daily check within plus or minus ten percent of the original curve?	
Are laboratory method blanks used as required?	
Is the standard calibration curve verified by running an additional standard within the range of the standard curve every 20 samples?	
Is this check within ten percent of the original curve?	

6. Review procedures for data handling, reporting and recordkeeping	Y/N/NA
Are computerized and/or manual checks applied at various appropriate levels of the measurement process to ensure data validation?	
Is the criteria for data validation documented and are limits on operational parameters, calibration data, special checks, statistical tests, and manual checks included?	
Does the laboratory have procedures for data handling and reporting, including the recording of data on standard forms and in laboratory notebooks?	
If so, is the reporting format for different types of bench data described and the forms provided?	
Are sample calculations available for inspection?	
Are bound notebooks used for all laboratory activities?	
Is raw data being archived and documented properly?	
Are records readily available for review?	
Are records maintained for a minimum of three years?	

NOTES

7. Review analytical procedures and evaluate their appropriateness (optional task)

*In certain cases, the inspector may wish to evaluate specific analytical procedures used in the laboratory as part of the inspection effort. *The purpose of this evaluation is to judge how faithful the laboratory's personnel are to analytical procedures as described in such references as Test Methods for Evaluating Solid Wastes (SW-846, November 1986). Due to the complexity and number of analytical procedures used to analyze ground-water samples, the inspector will need to construct checklists specific to procedures of interest. A procedure-specific checklist should allow the inspector to follow procedures on a step-by-step basis in the laboratory and detect departures from acceptable methodology. Areas of interest which could be factored into a checklist are as follows:*

- volume of sample processed (e.g.: digested, distilled, extracted, etc.);
- thoroughness of extraction (e.g.: digested to near dryness, use of and volume of correct acids, oxidizers, other modifiers, etc.);
- thoroughness of extraction (e.g.: number of times extracted, vigorousness of each extraction, use of and volume of correct solvent, etc.);
- frequency of sample preservation checks (e.g.: spot-checking sample pH and temperature conditions upon receipt at laboratory.);
- storage of samples in custody of laboratory awaiting analysis (e.g.: refrigeration at 4°C.);
- holding times of samples prior to analysis (e.g.: comparison of laboratory records of date and time analyzed vs. date and time sampled with acceptable holding times.);
- adequacy of standards preparation procedures (e.g.: actual preparation of stock, intermediate and working standards, dilution techniques, shelf life, etc.);
- instrumentation set-up techniques (e.g.: signal optimization, tuning, peaking, etc.);
- sample introduction techniques (e.g.: solvent-flush injection vs. a direct or straight injection, micro-pipettes usage, single vs. multiple injections, etc.); and
- quantification techniques (e.g.: peak area of sample vs. area of standard, peak height of sample vs. height of standard, linearity over concentration, etc.).

* It is important to note that most LAIs will probably not include an intensive review of analytical procedures. Reviews of this type should always be conducted by an experienced analytical chemist.

NOTES

PART THREE

Compliance Decision Making

PART THREE

The laboratory inspector and the enforcement official will meet after the laboratory inspection and review Parts One and Two of the inspection form. The enforcement official and the laboratory inspector will identify evidence of violations in the owner/operator's analytical program. After completion of this exercise, the enforcement official will take one of the following actions:

- Take enforcement action in conjunction with enforcement counsel for violations uncovered by the laboratory inspector; OR—

- Initiate a Case Development Inspection to gather additional information; OR—

- Take no follow-up action (no evidence of significant material violations).

It is important to note that many owner/operators choose to contract with commercial laboratories to perform ground-water analyses on their behalf. Questionable performance on the part of the commercial laboratory will be viewed by EPA as questionable performance on the part of the owner/operator. EPA will initiate enforcement actions against the owner/operator in cases where the commercial laboratory is generating questionable quality data or engaging in questionable laboratory practices.

It is also important to note that an individual laboratory may, in fact, conduct ground-water analysis for a number of owner/operators. The enforcement official should consider initiating as many enforcement cases as necessary when a laboratory is found deficient. In other words, the enforcement official should attempt to identify all owner/operators who use the services of the laboratory and, if warranted take concurrent enforcement actions against them. The enforcement official should, however, be aware that commercial laboratories may handle samples from other owner/operators according to separate and different operating procedures as dictated in an owner/operator's contract with that laboratory. The *Operation and Maintenance Inspection Guide—RCRA Ground-Water Monitoring Systems* (March 1988) provided for the collection of laboratory information from owner/operators in the course of O&M inspections (see page B-15). The enforcement official may use this information to help make decisions on initiating concurrent enforcement actions in the wake of a laboratory audit inspection.

1. Use **Table 4** to summarize technical inadequacies uncovered by the laboratory inspector.

2. Choose one of the following options:

   ☐ By virtue of evidence collected by the laboratory inspector, there are sufficient grounds to take enforcement action. Work with enforcement counsel to develop and initiate an enforcement action. OR—

   ☐ By virtue of evidence collected by the laboratory inspector, there may be sufficient grounds to pursue an enforcement action, however, additional or more detailed information is required. Initiate a Case Development Inspection. OR—

   ☐ The laboratory inspection has not uncovered significant compliance problems at the laboratory. Do not pursue additional enforcement action.

APPENDIX A
TABLE 4

SUMMARY OF TECHNICAL INADEQUACIES

This table illustrates examples of technical inadequacies which may constitute regulatory noncompliance on the part of the owner/operator. The enforcement official should apply this table on a case-specific basis in determining if an enforcement action is warranted. Table 1 lists the regulations which provide enforcement officials with the authority to conduct the LAI. Regulatory objectives inherent in these regulations are listed below along with examples of technical inadequacies which may prevent an owner/operator from satisfying the regulatory objectives.

Note: The owner/operator may choose to use a commercial laboratory. ***The owner/operator is responsible for the conduct of that laboratory.*** *This checklist was constructed with that concept in mind. Thus, the terms "owner/operator" and "laboratory" are used interchangeably in this checklist. O/O refers to owner/operator.*

Regulatory Objectives	Examples of Technical Inadequacies Which May Constitute Violations
1. Owner/operator (O/O) should follow specified procedures in analyzing ground-water samples.	• Failure of O/O to follow written sampling and analysis plan for analyzing ground-water samples (interim status). • Failure of O/O to follow permit conditions related to analysis of ground-water samples (permit status).
2. The O/O's laboratory should employ qualified staff to manage and carry out laboratory responsibility.	• Failure of O/O to develop Quality Assurance procedures which include: 1) ensuring adherence to Quality Assurance requirements for sampling; 2) ensuring that all test measuring equipment are properly calibrated; 3) monitoring logging in of samples; 4) approving project plans, specific analyses, and final reports; 5) maintaining a copy of the master schedule sheet; 6) maintaining separate copies of all methods performed by the laboratory;

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
2. The O/O's laboratory should employ qualified staff to manage and carry out laboratory responsibility. (Continued.)	7) maintaining written and signed records of periodic inspections; and 8) maintains all Quality Assurance records in one location. • Failure of O/O to authorize qualified individuals to approve data and results. • Failure of O/O to prepare a current summary of training, experience and job description for each member of the laboratory staff.
3. The O/O's laboratory should have suitable equipment for conducting analyses. The O/O's laboratory should have suitable procedures in place to ensure the quality of materials used in laboratory analyses.	• Failure of O/O to supply sufficient facilities and adequate laboratory instruments to perform required analyses. • Failure of O/O to properly vent solvent storage area as appropriate for the retention of possible laboratory contamination. • Failure of O/O to have analytical and sample storage areas isolated from all atmospheric sources of solvent. • Failure of O/O to date chemicals upon receipt and use on a first-in, first-out basis. • Failure of O/O to use reagent grade or high purity chemicals to prepare standards. • Failure of O/O to test chemicals being used in analyses to ensure that they contain no contaminants which may interfere with analyses. • Failure of O/O to label all reagents and solutions to indicate identity, concentration, storage requirements, preparer's name, preparation date, and expiration date. • Failure of O/O to have a source of distilled/ demineralized water.

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
3. The O/O's laboratory should have suitable equipment for conducting analyses. The O/O's laboratory should have suitable procedures in place to ensure the quality of materials used in laboratory analyses. (Continued.)	• Failure of O/O to routinely check and record the conductivity of distilled/demineralized water. • Failure of O/O to use reagent grade water for organic methods. • Failure of O/O to use distilled water for inorganic methods. • Failure of O/O to discontinue using any reagents and/or solutions that have passed the expiration date on the label. • Failure of O/O to use a service contract or internal protocol for maintaining instruments. • Failure of O/O to use internal protocol to manufacturer's specifications. • Failure of O/O to have available extensive in-house replacement parts. • Failure of O/O to maintain a service record logbook for each analytical instrument. • Failure of O/O to properly vent and/or have traps in place for instruments. • Failure of O/O to define and follow chemical waste disposal policies/procedures. • Failure of O/O to dispose of chemical waste in the proper area.
4. The O/O's laboratory should use suitable calibration and analytical procedures.	• Failure of O/O to store or use samples and/or standards containing the analyte(s) of interest in areas other than where trace analysis is performed. • Failure of O/O to store standards separately from sample extracts.

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
4. The O/O's laboratory should use suitable calibration and analytical procedures. (Continued.)	• Failure of O/O to have in chemical handling areas either a stainless steel bench or an impervious material covered with absorbent materials. • Failure of O/O to provide contamination-free areas for trace level or organic analytical work. • Failure of O/O to provide exhaust hoods to allow contamination-free work with volatile materials. • Failure of O/O to periodically check and record the air flow of the hoods. • Failure of O/O to make available manufacturer's operating manuals to the operator. • Failure of the O/O to implement required or appropriate analytical methodology such that data is so inaccurate or imprecise as to preclude its use. • Failure of O/O to make available to the analyst all methods in approved written format. • Failure of O/O to make available to the analyst calibration procedures, analytical procedures, computational procedures, quality control procedures, and operating procedures. • Failure of O/O to make available reference material for each analysis to help analysts investigate problems. • Failure of analyst to have schedule for all analyses they perform. • Failure of analyst to have an analysis request sheet (if no schedule is available) for each sample they must perform an analysis on. • Failure of O/O to specify initial and daily instrument calibration procedures in QA/QC program.

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
4. The O/O's laboratory should use suitable calibration and analytical procedures. (Continued.)	• Failure of O/O to use above specified procedures in daily laboratory analysis. • Failure of O/O to use standard curves and check samples covering the analytical range of interest for calibrating analytical instruments to ensure that calibration accurately encompass the range of environmental samples. • Failure of O/O to maintain a log of all instruments and equipment checks. • Failure of O/O to assign lab personnel to perform the calibration procedures. • Failure of O/O to deem an analytical system "out of control" when accuracy and precision of matrix spikes and/or surrogates fall outside specific limits. • Failure of O/O to stop an analysis and implement corrective procedures when an analytical system is deemed "out of control." • Failure of O/O to clearly define corrective procedures. • Failure of O/O to assign individuals to the responsibility of initiating corrective procedures if the individual deems necessary. • Failure of O/O to document "out of control" situations and corrective procedures used in getting a system back in control. • Failure of O/O to notify about errors in reporting data or "loss" of a sample and failure to request resampling from same point. • Failure of O/O to use Class A type glassware or calibrate to ensure that the amount marked on the glassware coincides with the amount delivered.

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
4. The O/O's laboratory should use suitable calibration and analytical procedures. (Continued.)	• Failure of O/O to check glassware to ensure calibration is correct. • Failure of O/O to correctly clean glassware after each use to ensure that there will be no contamination with the next use. • Failure of O/O to locate analytical balance away from drafts and areas subject to rapid temperature change. • Failure of O/O to calibrate and check analytical balance at least once per year by a certified technician.
5. The O/O and the O/O's laboratory should use proper sample handling procedures.	• Failure of O/O to appoint an individual to log in incoming samples. • Failure of O/O to make individuals logging in samples aware of sampling requirements for each analysis. • Failure of O/O to make individuals aware of the storage process for storage of incoming samples. • Failure of O/O to affix sample labels to each container. • Failure of O/O to have complete information on sample labels in order to identify the sample and ensure that it has been sampled in the correct manner. • Failure of O/O to collect samples in the correct type of container specified for each analysis. • Failure of O/O to preserve sample for preservation when required.

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
5. The O/O and the O/O's laboratory should use proper sample handling procedures. (Continued.)	• Failure of O/O to ensure that samples shipped to the laboratory arrive at the correct temperature so as to remain in the preserved state. • Failure of O/O to ship volatile samples with *no air* bubbles. • Failure of O/O to use transport blanks, field blanks, and field duplications as required. • Failure of O/O to identify all blanks and spiked samples to ensure no mix-up occurs. • Failure of O/O to fill out chain-of-custody and keep it on file. • Failure of O/O to ensure information on chain-of-custody and sample tag match. • Failure of O/O to assign laboratory numbers to all incoming samples. • Failure of O/O to maintain a master schedule sheet or logbook of all samples being analyzed, indexed by laboratory numbers, client, date of arrival, and analysis to be performed. • Failure of O/O to write the laboratory number of a sample on the sample label, the master schedule sheet, and any documents related to that sample. • Failure of O/O to provide complete sample analysis request sheet for each sample. • Failure of O/O to provide a separate analysis request sheet for each analysis or group of analyses. • Failure of O/O to attach all request sheets together with all appropriate summary sheets for each analysis.

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
5. The O/O and the O/O's laboratory should use proper sample handling procedures. (Continued.)	• Failure of O/O to analyze samples within a correct amount of time. • Failure of O/O to maintain samples at correct temperature until time of analysis. • Failure of O/O to provide adequate facilities for storage of incoming samples. • Failure of O/O to store volatile samples separately from non or semi-volatile samples. • Failure of O/O to record temperature of cold storage daily in a logbook. • Failure of O/O to note temperature excursions and take appropriate action when required. • Failure of O/O to properly clean sample containers for reuse.
6. The O/O's laboratory should have in-place a suitable quality control program.	• Failure of owner operator to measure accuracy results of matrix spikes and surrogates for each method. • Failure of O/O to measure precision results of each matrix spikes and surrogates for each method. • Failure of O/O to use precision and accurate results to determine the specific limits in which all operating parameters will be kept. • Failure of O/O to analyze matrix spikes and surrogates to establish that the instrument is functioning properly with the desired sensitivity. • Failure of O/O to organize precision and accuracy results in the form of quality control charts.

Regulatory Objectives	Examples of Technical Inadequacies That May Constitute Violations
6. The O/O's laboratory should have in-place a suitable quality control program. (Continued.)	• Failure of O/O to use quality control charts or equivalent to document validity of data on an as-run basis.

APPENDIX B

RCRA Laboratory Audit Inspection Guide

(RCRA Ground-Water Monitoring Systems)

Questions and Answers

Lab Audit Guidance
Questions and Answers

1. Is the RCRA Laboratory Audit Inspection the same as a CERCLA Contract Lab Inspection?

No. The objectives of the CERCLA Contract Lab Program and the RCRA LAI are very different. EPA has designed the CERCLA contract lab program to ensure that commercial laboratories which provide analytical services for EPA and the states are consistently producing reliable quality analytical data. EPA has designed the RCRA LAI to ensure owner/operators are meeting their regulatory responsibilities to generate reliable quality data. The evaluation one would make of a CERCLA contract laboratory and a RCRA commercial laboratory is, however, very similar regarding to what the inspector(s) would evaluate and how they would make decisions as to the quality of analytical data produced by the laboratory.

2. What is the relationship between a RCRA Lab Audit Inspection, the Comprehensive (Ground-Water) Monitoring Evaluation (CME), and the Operation and Maintenance (O&M) Inspection?

The CME, LAI and O&M inspection all have one step in common: they all involve the review of the owner/operator's ground-water sampling and analysis program. The CME, however, is primarily geared toward a review of the owner/operator's ground-water monitoring system from a design standpoint. The O&M inspection focuses on the field implementation of the owner/operator's sampling program. The LAI focuses on the laboratory implementation of the owner/operator's sampling and analysis program. Collectively, they represent a comprehensive and continuous review and analysis of the design and implementation of an owner/operator's ground-water monitoring program.

3. Does the RCRA Laboratory Audit Inspection require an analytical chemist to conduct the laboratory inspection?

Yes. The laboratory inspection portion of the LAI requires a qualified analytical chemist (or equivalent). This chemist must be able to review and critically analyze how well laboratory personnel are discharging their duties in regards to the analysis of RCRA ground-water monitoring samples. The chemist or equivalent should also attempt to determine the effects or biasing caused by any questionable laboratory practices identified.

4. Does EPA have a lab certification program for those laboratories conducting RCRA analyses?

No. EPA does not certify laboratories which conduct analyses for RCRA owner/operators. The LAI is not a certification procedure.

5. During the course of a RCRA Laboratory Audit Inspection, the enforcement official finds that a laboratory engages in questionable analytical procedures. May the enforcement official assume these practices affected the analysis of the owner/operator's samples over time?

Yes. It is reasonable to assume that questionable practices detected during a LAI are problems which have existed prior to the LAI. The enforcement official may take enforcement actions on the basis of problems found during an LAI.

6. If an owner/operator's facility is in EPA Region A and laboratory facilities are in EPA Region B, what should the Regions do to ensure an efficient and coordinated inspection effort?

Region A and Region B should consider a joint inspection effort and/or Region A should ask Region B to conduct the inspection on behalf of Region A. Since any potential enforcement action will be pursued against the owner/operator (Region A), Region A enforcement officials should take the lead in issuing the complaint.

7. If a RCRA LAI ultimately results in a questioning of the veracity of analytical procedures/practices employed by the owner/operator's laboratory, should the enforcement official reject data collected to date by the owner/operator?

Probably. In some cases, past data may be able to be reconstructed or used to some useful purpose. In other cases, past data may be worthless. In these cases, the enforcement official should take an enforcement action to require the owner/operator to collect a full set of data as quickly as possible. The enforcement official may consider monetary penalties equal to the cost the owner/operator avoided in collecting high quality data (i.e., penalty equals cost of re-creating past data).

8. A Laboratory Audit Inspection uncovers a laboratory which engages in poor analytical practices. The enforcement official is concerned that the laboratory is conducting analyses for other RCRA facilities. What should the enforcement official do?

The enforcement official should attempt to uncover the names of other firms for which the laboratory conducts ground-water analyses. The enforcment official may then consider pursuing enforcement actions against all owner/operators who use the services of the laboratory. The enforcement official should, however, be aware that commercial laboratories may handle samples from other owner/operators according to separate and different operating procedures as dictated in an owner/operator's contract with that laboratory.

9. Assume that an owner/operator uses a commercial laboratory to perform RCRA analyses of ground-water samples. The Laboratory Audit Inspection leads an enforcement official to doubt the veracity of the analytical data produced by the laboratory. Who is in violation—the commercial laboratory or the owner/operator who hired them?

EPA would only take enforcement action against the owner/operator. It is the responsibility of the owner/operator to ensure that those parties who provide services to support a regulatory requirement are, in fact, dischaging their responsibilities in an acceptable manner. Questionable performance by a laboratory is not an acceptable excuse for regulatory noncompliance by the owner/operator.